

DETAILED ACTION

Claims 1-27 are currently pending. Claims 1-15 are currently under examination.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-15, in the reply filed on 01/25/2010 is acknowledged.

Claims 16-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/25/2010.

Applicant's election without traverse of Pullulan, polyvinylpyrrolidone and a blend of cetyltrimethylammonium chloride and polyethylene glycol-40 in the reply filed on 01/25/2010 is acknowledged.

No claims are withdrawn as a result of the species election.

Priority

Priority is claimed to German Application 10 2004 002 951.1, filed 01/21/2004 and International Application 01/11/2005.

Information Disclosure Statement

Applicant's Informational Disclosure Statement, filed on 07/19/2006 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Specification

The abstract of the disclosure is objected to because reference is made to EP 1 137 916 (page 1, line 27). Examiner believes Applicant intended to make references to EP 1 317 916. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recited 'a method for producing a hair fixing product in the form of a foil'. Applicant's specification contains no definition of a foil.

The Free Dictionary defines foil to be 'a thin, flexible leaf or sheet of metal (TheFreeDictionary, middle of the page). The instant claims are directed to a foil which is not metal, but polymeric. Examine is interpreting foil to mean a thin sheet.

Clarification is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 317 916 (publication date: 06/11/2003, cited on IDS dated 07/19/2006) in view of JP 62072609 (publication date: 04/03/1987, cited on IDS dated 07/19/2006).

The '916 publication teaches a film useful for delivering a variety of agents including fragrances (abstract). Many of the marketed films contain pullulan as the main component (page 2, paragraph [0004]). The films that are taught are wetted when exposed to water, followed by rapid dissolution and/or disintegration (page 2, paragraph

Art Unit: 1615

[0006]). The starch component may also comprise a cellulosic material or gum, such as pullulan, which is fully compatible and essentially substitutable for the starch (page 3, paragraph [0022]). At least one film strengthener may be added to enhance the mechanical properties without substantially increasing the dissolution or disintegration time of the film. Film strengtheners useful in the instant invention include polyvinylpyrrolidone. The film strengtheners may be present in any desired amount, particularly from 0 to 5% by weight of the starch component (page 4, paragraph [0027]). Optional components that may be added to the composition include humectants (page 4, paragraph [0028]). A particularly suitable process for preparing the films of the present inventions by preparing a coating formulation by making a solution or dispersion of the film components, applying the mixture to a substrate, suing a knife coating methods, drying the coated substrate to remove the majority of the solvent and removing the film from the substrate (page 4, paragraph [0030]). The film is not completely dry in the some degree of water or other solvent remains. The amount of water may be controlled to obtain desired functionality. For example, more water typically results in a more flexible film, too much water results in a film which will block and be tacky (page 4, paragraph [0031]). The film thickness will depend in part on the desired end use. Typically the film thickness will be in the range of about 1 to 500 microns, particularly 25 to 100 microns (page 4, paragraph [0032]). The films are cast using a knife-over-roll coating method and air dried overnight (page 7, paragraph [0041]). A hair fixative is taught containing polyvinylpyrrolidone as the hair fixative. The mixture contains 90 g of starch, 210 g of water and 10 g of polyvinylpyrrolidone. The

mixture is homogenized and then drawn into a film and dried (page 9, example 8, paragraphs [0055]-[0056]).

The '609 publication teaches a water soluble sheet comprising pullulan.

Polyvinylpyrrolidone is taught to be used to raise film forming properties. The product is in the form of a sheet and is used for personal care (Abstract).

The '916 publication teaches a hair fixation sheet which comprises starch and polyvinylpyrrolidone. The '916 publication further teaches pullulan is used in most films as the main component, and pullulan can be used to replace starch in the formulations. The '609 publication further demonstrates that pullulan and polyvinylpyrrolidone can be used in combination to form a sheet used for personal care. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use pullulan and polyvinylpyrrolidone in a thin film for hair fixation based on the teachings of the '916 publication and the '609 publication.

Regarding claim 1, the '916 publication teaches a method of preparing a hair fixing film by combining water, starch and polyvinyl pyrrolidone and homogenizing, drawing into a film using a knife-over-roll coating and drying overnight. The '916 publication pullulan is used as the main component in most films and can be substituted for the starch component. The '609 publication further demonstrates pullulan and polyvinylpyrrolidone can be used in combination to make a personal care film.

Regarding claims 2, 6-7, 9 and 11-12, the combination of references teaches the film containing the elected pullulan and polyvinylpyrrolidone.

Regarding claim 3, the solvent is taught to be water by the '916 publication.

Regarding claims 4 and 10, the '916 publication teaches example 8 comprising a composition containing starch (90 g), water (210 g) and polyvinylpyrrolidone (10 g). The composition contains 29% starch (pullulan upon substitution), 67% water and 3% polyvinylpyrrolidone.

Regarding claim 5, the '916 publication teaches drying overnight and also teaches the amount of water in the final composition can be optimized to vary the film flexibility. It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the amount of water in the final film composition in order to obtain the desired film flexibility, absent evidence to the contrary.

Regarding claim 13, the '916 publication teaches the film including a fragrance.

Regarding claim 14, the film thickness is taught to be 25 to 100 microns as is taught by the '916 publication.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 317 916 (publication date: 06/11/2003) and JP 62072609 (publication date: 04/03/1987) as applied to claims 1-7 and 9-14 above, and further in view of US 4,562,020 (patent date: 12/31/1985).

As mentioned in the above 103(a) rejection, all the limitations of claims 1-7 and 9-14 are taught by the combination of the '916 publication and the '609 publication. The combination of references does not teach the molecular weight of pullulan.

The '020 patent teaches a self-supporting glucan film comprising an aqueous glucan solution where the glucan is taught to be pullulan (abstract). Generally pullulan

is taught to have an average molecular weight in the range of 50,000 to 5,000,000 (column 3, lines 37-41).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use pullulan at the molecular weight of the 50,000-5,000,000 as the '020 patent teaches that to be the average molecular weight of pullulan used in a self supporting film. It would be obvious to one of ordinary skill in the art at the time the invention was made to use pullulan in a film at a molecular weight range which is known to be used in films.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 317 916 (publication date: 06/11/2003) and JP 62072609 (publication date: 04/03/1987) as applied to claims 1-7 and 9-14 above, and further in view of US 5,393,528 (patent date: 02/28/1995).

As mentioned in the above 103(a) rejection, all the limitations of claims 1-7 and 9-14 are taught by the combination of the '916 publication and the '609 publication. The combination of references does not teach introducing gas bubbles into the foil.

The '528 patent teaches a dissolvable material used for local administration of an agent to the body area. The material is taught to dissolve due to human body temperature and moisture during use. The dissolving element may be foamed as a means for increasing its dissolution rate (abstract). There is an addition of gases in the formation of the film in order to alter the texture and solubility of the film (column 3, lines 15-20). The film characteristics may be altered by adding the appropriate amounts of

Art Unit: 1615

gas, such as air, nitrogen or other inert gases, which can produce a more acceptable film texture and modify the dissolution rates accordingly. It has been surprisingly found that the addition of nitrogen or other inert gas to a PVA film haves the dissolution rate of the film (column 8, lines 23-30).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to introduce inert gas into the film taught by the combination of the '916 publication and the '609 publication because the '528 publication teaches introduction of gas into a polymer film can be used to alter dissolution rates and provide more acceptable feel of the film. One of ordinary skill in the art at the time the invention was made would have a high expectation of success in altering the dissolution rate of the film taught by the combination of the '916 publication and the '609 publication by addition of an inert gas because the '916 publication and the '609 publication teach polymeric films which dissolve upon contact with water and the '528 publication teaches changes of dissolution rate in a polymeric film which dissolves by temperature and body moisture by incorporation of gas into the film.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNDSEY BECKHARDT whose telephone number is (571)270-7676. The examiner can normally be reached on Monday thru Thursday 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYNDSEY BECKHARDT/
Examiner, Art Unit 1615

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